

REMARKS

After entry of this amendment, claims 1-14 are pending, claims 1, 2, and 12-14 are directed to the elected invention and claims 3-11 are withdrawn.

Reconsideration is respectfully requested of the rejection of claims 1 and 2 as anticipated by Meyers (U.S. Patent No. 5, 420, 161). An anticipating reference must disclose all of the elements of the claims.

Meyers generally discloses methods of weight and appetite suppression by administration of various doisylnolic acid compounds. Although Meyers does describe methods of producing weight loss and appetite suppression using a small genus including (+)-Z-bisdehydrodoisylnolic acid, the reference is silent on the element of instant claim 1 requiring the repression of weight gain or reduction in weight being independent of food intake. In contrast, claim 8 of Meyers is a method for suppressing appetite. Thus, the Meyers reference does not disclose or suggest the requirement of the repression of weight gain being independent of food intake.

As noted in M.P.E.P. §2112.IV, a rejection based upon the inherency of a claimed element must be supported by evidence that the missing element is necessarily present in the reference:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). . . .

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow

molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Applicants respectfully submit that the present rejection is not supported by objective evidence or cogent technical reasoning to support the conclusion of inherency with regard to the weight loss being independent of food intake. Absent such evidence or reasoning, anticipation has not been established and the burden of proof has not shifted to the applicant to prove that the alleged inherent weight loss being independent of food intake is not necessarily present in the cited reference.

For example, Meyers discloses data regarding weight loss for administration of (±)-Z-BDDA only. In contrast, Table 1 on page 63 of the instant specification, compares the administration of estradiol, (±)-Z-BDDA, and (+)-Z-BDDA to male and female rats. When compared in experiments described in the instant specification, the food efficiency ratio of (+)-Z-BDDA is significantly different and significantly lower than the food efficiency ratio of (±)-Z-BDDA when administered to male rats at the same dosage. When male subjects and the (+)-Z-BDDA isomer are selected as they are in instant claim 1, the requirement of the weight repression being independent of food intake is not necessarily present in the disclosure of Meyers. Consequently, there is no teaching in Meyers of administering (+)-Z-BDDA specifically to males, much less any express or inherent disclosure of administering (+)-Z-BDDA to males at a dosage that would suppress weight gain independently of food intake. Therefore, the Meyers reference does not anticipate claims 1 and 2.

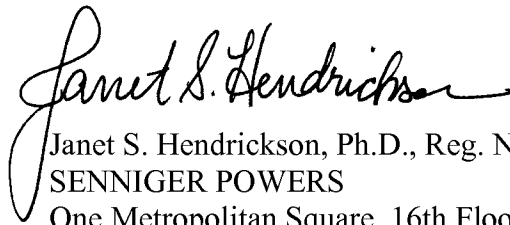
Instant claims 12-14 depend from claim 1 and further require either a decrease in food efficiency, that the repression of weight gain or reduction in weight is not due to appetite suppression, or that there is not a decrease in food intake of the male patient. These claims are not anticipated by the Meyers reference for the same reason as claim 1.

CONCLUSION

Applicant submits that the present application is now in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, reading "Janet S. Hendrickson", with a stylized flourish at the end.

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